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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/670,118	09/24/2003	Salim Yusuf	16554-002002 / H31086-USC	2545

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EXAMINER	
NGUYEN, BAO THUY L	

ART UNIT	PAPER NUMBER
1641	

MAIL DATE	DELIVERY MODE
03/14/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/670,118	YUSUF ET AL.	
	Examiner	Art Unit	
	Bao-Thuy L. Nguyen	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10 and 16-25* is/are pending in the application.

4a) Of the above claim(s) *1-10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02 January 2008 has been entered.

Status of the Claims

2. Claims 1-10 have been withdrawn. Claims 11-15 have been canceled. Claims 16-25 have been added are and pending.

Priority

3. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent

application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosures of the prior-filed Application No. PCT/CA03/00422 and US 60/367,883, fail to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application.

Claim 16 is directed toward a test kit comprising a first strip having a test patch with a predetermined amount of labeled antibody, and a second strip for absorbing a test sample. Such a device is not adequately supported by the specification of 60/367,883. The provisional document is limited to a device containing reagents specific for thromboxane, i.e. anti-thromboxane antibody. Furthermore, nowhere in the specification of 60/367,883 is there a disclosure of a device comprising a strip having a plurality of standard patches as claimed in 17 and 22. The *reference marks* disclosed by '883 do not provide adequate support for *standard patches having a predetermined amount of reporter molecules.*

Therefore, this application is only entitled to the instant filing date of 24 September 2003.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20, 21 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 20 and 21 do not further limit claim 16 because samples and analytes are not normally part of a kit. They are often not collected until the time of the assay.

Claim 23 is vague because it is unclear how the level of creatinine relates to thromboxane B2.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 16, 17 and 19 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Clemmons (US 5,030,555).

Claim 16 is limited to a kit comprising a first strip having labeled antibody thereon and a second strip for absorbing test sample. The intended use of the strips is not given patentable weight. If the prior art structure is capable of performing the intended use, then it meets the claim.

Clemmons discloses a "dip-stick" type device on which is located a plurality of test pads (102a-d). Each test pad is secured to a backing strip (104). Each test pad includes a porous membrane 106 (i.e. second strip) attached to the support member around the periphery thereof. A matrix (108) is positioned between the membrane and the support member. The test pads have antibodies absorbed thereon on the side of the membrane adjacent to the matrix, while the matrix contains labeled antibody (i.e. first strip having antibody bound to a reporter molecule). See column 8, lines 10-68. In use, sample fluid enters through the membrane 106 and into the matrix 108. Analytes in the sample is captured by the antibody bound to membrane 106. Fluid entering matrix 108 mobilizes the labeled antibody 112 to form a labeled immunoreagent-analyte-antibody sandwich bound to the membrane 106. See column 9, lines 1-41.

With respect to claim 17, Clemmons discloses at least four test pads containing predetermined amount of labeled reagent to detect analytes. See example 4.

With respect to claim 19, Clemmons discloses the use of enzyme labels. See column 7, lines 16-21.

Even though Clemmons does not specifically teach a kit comprising the test strips, the kit of the instant invention is nothing more than the test strips themselves,

and since Clemmons anticipates the test strips, Clemmons is seen to disclose the invention as claimed.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 20-23, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clemmons in view of Reinke et al (IDS – AT)

Clemmons differs from the instant invention in failing to teach that the device can detect thromboxane B2.

Reinke, however, discloses the importance of detecting thromboxane B2 and teaches assays for their detection. Reinke discloses thromboxane B2-BSA conjugates, monoclonal antibodies specific to thromboxane B2 and three different types of enzymes detection system.

Even though the instant claims are not limited to reagents specific for thromboxane B2, the device of kit can be adapted carry reagents specific for the recited analyte. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device taught by Clemmons to detect

thromboxane B2 using the reagents taught by Reinke because Clemmons teaches that their device is suitable for a variety of analytes with the choice of appropriate reagents. A skilled artisan would have had a reasonable expectation of success in using the device taught by Clemmons to detect thromboxane B2 because Reinke teaches that the measurement of thromboxane is important because an increase in biosynthesis of thromboxane is observed in patients with coronary diseases as well as a hosts of other problems, and Clemmons teaches that their device is unique in that it can be readily and easily used or performed by minimally trained personnel.

9. Claims 18 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clemmons in view of Reinke as applied to claim 16 above, and further in view of Guire (US 4,826,759).

Clemmons and Reinke are discussed above. These references differ from the instant invention in failing to teach the use of dyes as labels.

Guire discloses both enzymes and leuco dyes as labels in an immunoassay. See column13.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the enzyme label taught by Clemmons and Reinke with the leuco dyes taught by Guire because they are functionally equivalent.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Monday -- Thursday from 9:00 a.m. - 3:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bao-Thuy L. Nguyen/
Primary Examiner, Art Unit 1641